

### **REMARKS**

Claims 1-28, 58 and 60 are pending. Claims 62-73 are newly added. Claim 59 is newly canceled without prejudice. Claims 1-9, 12-14, 19, 22-28, 58 and 60 are newly amended. The claim amendments find support in the specification and are discussed below. No new matter has been entered.

Specifically, newly added claims 62-64 encompass a peptide consisting of an amino acid sequence of SEQ ID NO:16 or SEQ ID NO:22. The amino acid sequence of SEQ ID NO:22 has two additional amino acids (Asp and Ile) at the C-terminus of the amino acid sequence of SEQ ID NO:16.

#### ***Drawings***

The office action states that Figure 4 is objected to because the description of the figure in the specification is referred to as “Fig. 4A”, but the replacement figure is not labeled “Fig. 4A”. Applicant has amended the specification so that the drawing and the specification read the same.

#### ***Specification***

The office action indicates that the disclosure is objected to because page 15, line 29, recites “amide oe or ester”. Applicant has amended the specification to correct the spelling in this phrase.

#### ***35 U.S.C. 112, second paragraph***

The office action indicates that claims 1, 10 and 12-14 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the office action contends that it is unclear what limitation the phrase “a methionine residue at the N-terminus is optionally formylated” places on the claimed peptide, especially in embodiments that are not required to have a methionine at the N-terminus.

Applicant has amended the instant claims to more clearly define the claimed invention by including the phrase “if any” immediately following the recitation of

“methionine residue at the N-terminus”, so that claim 1 recites “.....methionine residue at the N-terminus, if any, is optionally formylated..”. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 2 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what limitation the phrase “ a methionine residue at the N-terminus is optionally formylated” places on the claimed peptide, especially in embodiments that are not required to have a methionine at the N-terminus. Applicant has amended the instant claims to more clearly define the claimed invention by including the phrase “if any” immediately following the recitation of “methionine residue at the N-terminus”, so that claim 2 recites “.....methionine residue at the N-terminus, if any, is optionally formylated..”. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claims 3 and 4 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what limitation the phrase “ a methionine residue at the N-terminus is formylated” places on the claimed peptide, especially in embodiments that are not required to have a methionine at the N-terminus. Applicant has amended the instant claims to more clearly define the claimed invention by including the phrase “if any” immediately following the recitation of “methionine residue at the N-terminus”, so that claims 3 and 4 recite “.....methionine residue at the N-terminus, if any, is optionally formylated..”. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 5 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what limitation the phrase “ a methionine residue at the N-terminus is formylated and an isoleucine residue at the C-terminus is modified” places on the claimed peptide, especially in embodiments that are

not required to have a methionine at the N-terminus and/or an isoleucine residue at the C-terminus. Applicant has amended the instant claims to more clearly define the claimed invention by including the phrase “if any” immediately following the recitation of “methionine residue at the N-terminus”, so that claim 5 recites “.....methionine residue at the N-terminus, if any, is formylated and an isoleucine residue at the C-terminus if any, is modified..”. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claims 6, 7 and 11-14 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what limitation the phrase “a methionine residue at the N-terminus is optionally formylated” places on the claimed peptide, especially in embodiments that are not required to have a methionine at the N-terminus. Applicant has amended the instant claims to more clearly define the claimed invention by including the phrase “if any” immediately following the recitation of “methionine residue at the N-terminus”, so that claims 6 and 7 recite “.....methionine residue at the N-terminus, if any, is optionally formylated..”. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claims 8 and 9 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what limitation the phrase “a methionine residue at the N-terminus is formylated” places on the claimed peptide, especially in embodiments that are not required to have a methionine at the N-terminus. Applicant has amended the instant claims to more clearly define the claimed invention by including the phrase “if any” immediately following the recitation of “methionine residue at the N-terminus”, so that claims 8 and 9 recite “.....methionine residue at the N-terminus, if any, is formylated..”. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 3 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the office action contends that it is unclear what is meant by the recitation in claim 3 of the phrase “according to claim 1”. Accordingly, Applicant has amended claim 3 to be in independent form. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 4 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what is meant by the recitation in claim 4 of the phrase “according to claim 1”. Accordingly, Applicant has amended claim 4 to be in independent form. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 5 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what is meant by the recitation in claim 5 of the phrase “according to claim 1”. Accordingly, Applicant has amended claim 5 to be in independent form. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 8 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what is meant by the recitation in claim 8 of the phrase “according to claim 6”. Accordingly, Applicant has amended claim 8 to be in independent form. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 9 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what is meant by the recitation in claim 9 of the phrase “according to claim 6”. Accordingly, Applicant has amended claim 9 to be in independent form. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claims 15-23 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that the binding characteristics of

the claimed antibody are unclear given the variance in sequence of the peptides to which the antibody binds. Applicant contends that the genus of peptides to which the antibodies is clearly and definitely described, especially in view of claim amendments to claims 6 and 1, as described above. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 24 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that without method steps it is unclear how one screens a compound if the compound is not added to the mixture, and if no actual measurements are being assessed on the binding of the components (1) the receptor protein and (2) the peptide according to claim 1. Accordingly, Applicant has amended claim 24 by adding method steps to the instant claim. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 25 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that without method steps it is unclear how one screens a compound if the compound is not added to the mixture, and if no actual measurements are being assessed on the binding of the components (1) the receptor protein and (2) the peptide according to claim 6. Accordingly, Applicant has amended claim 25 by adding method steps to the instant claim. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 26 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that without method steps it is unclear how one screens a compound if the compound is not added to the mixture, and if no actual measurements are being assessed on the binding of the components (1) the receptor protein and (2) the peptide according to claim 1. Accordingly, Applicant has amended claim 26 by adding method steps to the instant claim. In light of the instant claim

amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 27 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what the metes and bounds of the components actually contained in the kits due to the claim language which refers to a kit which comprises “using” component (1) and component(2). Accordingly, Applicant has amended claim 27 by deleting the word “using” and including the kit components. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 28 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that it is unclear what the metes and bounds of the components actually contained in the kits due to the claim language which refers to a kit which comprises “using” component (1) and component(2). Accordingly, Applicant has amended claim 28 by deleting the word “using” and including the kit components. In light of the instant claim amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

The office action indicates that claim 58 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that claim 58 is dependent from canceled claims 29 and 31. Accordingly, Applicant has removed the dependency of this claim from canceled claims 29 and 31.

The office action indicates that claim 59 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action contends that claim 59 is dependent from canceled claims 29 and 31. The office action also indicates that that claim 59 provides for the use of a peptide, but does not set forth any method steps. Applicant has canceled claim 59 without prejudice, rendering these rejections moot.

The office action indicates that claim 60 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the office action contends that claim 60 is dependent from canceled claims 36 and 37. Accordingly, Applicant has removed the dependency of this claim from these canceled claims.

***35 U.S.C. 112, first paragraph***

Claim 58 is rejected under 35 U.S.C.112, first paragraph, because the specification while being enabling for purification of various proteins and in vitro binding assays, does not reasonably provide enablement for methods for preventing and/or treating the listed diseases. Specifically, the office action contends that the amount of direction or guidance in the specification is not sufficient for the extremely broad scope of the claims, encompassing prevention of the recited disease following the administration of the claimed peptides.

Applicant respectfully traverses the assertion in the office action that the claims are not enabled for the recited diseases. Applicant has newly amended the claims to recite those diseases in which a relationship between each of the currently recited diseases and the receptor FRPL1 has been published. Further, Applicant has attached scientific papers herein which describe the correlation between each of the recited diseases and receptor FRPL1. Specifically, Applicant has provided for asthma and allergic disease, the reference by Levy et al. (2002) Nat. Med. 8(9):1018-23; for inflammation, Takano et al. (1997) J.Exp. Med. 185(9):1693-704; for ocular infection, Huang et al. (2006) Invest Ophthalmol Vis Sci 47(6):2369-80; for lupus erythematosus, Bennet et al. (2003) J.Exp.Med 197(6):711-23; for psoriasis, O'Hara et al (2004) Arthritis Rheum. 50(6):1788-99; for Rheumatoid, osteoarthritis and synovitis, Hashimoto et al. (2007) J. Rheumatol. 34(11):2144-53; for cerebral infarction, Gavins et al. (2007) FASEB 21(8):1751-8; for edema, Zhou et al. (2007) Mol. Pharmacol. 72(4):976-83; for multiple sclerosis, Muller-Ladner et al. (1996) J. Neurol. Sci. 144(1-2):135-41; for Alzheimer's disease, Cui et al. (2002) J. Leukoc. Biol. 72(4):628-35; for AIDS, Deng et al. (1999) Blood 94(4):1165-73; for diabetes mellitus, Foris et al. (1998) Clin. Immunol. Immunopathol. 86(1):95-101; for ulcerative colitis, Keshavarzian et al. (1997) J. Lab. Clin Med. 130(2):216-25; for pneumonia, Fillion, I. J. Immunol 166(12):7353-61; for arteriosclerosis, Zhao et al. (2007) Arterioscler Thromb Vasc Biol 27(7):1645-50; for

viral infection, Le et al. (2001) Cytokine Growth Factor Rev 12(1):91-105 ; Gavins et al. (2005) Prostaglandins Leukoc Essent Fatty Acids 73(3-4):211-9; for immunodeficiency, Le et al. (2002) Int Immunopharmacol 2(1):1-13. Related terminology includes: ALXR, FMLP-related receptor I, FMLP-R-I, FMLP-R-II, FMLPX, Formyl peptide receptor-like 1, FPR2, FPR2A, FPRH1, FPRH2, HM63, Lipoxin A4 receptor, LXA4R, LXA4 receptor, and RFP .

Applicant contends that the FPRL1 ligand peptide of the instant invention has ligand activity or signal transduction activity through the receptor FPRL1, as demonstrated in Example 19 of the instant specification, in which a migration assay is described in which a FPRL1 ligand stimulated migration of CHO cells expressing FPRL1-GFP fusion protein. Applicant contends that in view of the ligand activity and/or signal transduction activity by the FPRL1 ligand peptide of the instant invention through the receptor FPRL1, and the correlation of this activity and the instantly recited disease described in the literature, it would not require undue experimentation by one of skill in the art to practice the claimed invention.

In light of the instant claim amendment and above remarks, Applicant respectfully requests reconsideration and withdrawal of the rejection.

### ***35 U.S.C. 101***

Claim 59 is rejected under 35 U.S.C. 101 because the claimed recitation of a use without setting forth any steps in the process, results in an improper definition of a process. Applicant has canceled claim 59 without prejudice, thereby rendering this rejection moot.

### ***Conclusion***

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.



Respectfully submitted,

Date: May 12, 2008

/Amy DeCloux/

Name: Amy DeCloux,  
Registration No.: 54,849

Name: David Conlin  
Registration No.: 27,026

Customer No.: 21874  
Edwards Angell Palmer & Dodge  
LLP

111 Huntington Avenue  
Boston, MA 02199-7613

Tel: 617-239-0100